Statement PhRMA

Statement of the Pharmaceutical Research and Manufacturers of America (PhRMA)
in Support of a Strong Regulatory Compliance Defense
February 21, 2012

Position: PhRMA supports the adoption of a strong regulatory compliance defense that would establish that no manufacturer or seller of a prescription drug will be held liable in products liability action if the drug and its label were approved by the United States Food and Drug Administration (FDA). This would not apply to manufacturers or sellers who have intentionally misrepresented the product to the FDA or participated in other such illegal actions.

Under a regulatory compliance defense, a pharmaceutical company could not be held liable if it fully complies with FDA's rigorous requirements, which include specifying the warnings that companies must provide about their products and submitting post-marketing reports on possible patient adverse reactions to the FDA. Notably, the defense would not be available if a manufacturer withholds information from, or misrepresents information to the FDA. It also would not be available if the drug's label was not consistent with the FDA's requirements. The adoption of a regulatory compliance defense is the proper balance to be struck between the rights of consumers and those of manufacturers who comply with rigorous FDA requirements.

Currently, product liability is determined by the laws of each state. This patchwork system increases healthcare costs, discourages innovation and can cause manufacturers to withdraw useful products from the market. In light of these uncertainties, the utility of a regulatory compliance defense is clear. Pharmaceutical manufacturers are frequently required by law to include certain warnings, yet are then potentially subject to liability because one jurisdiction's law is more stringent or is otherwise different than the next jurisdiction. The adoption of a regulatory compliance defense would help foster uniformity and provide some measure of predictability to industry. Government standards usually are derived from a partnership between government and industry, and are the result of the thoughts and opinions of many persons, often people with a great deal of scientific and medical expertise and years of practical experience with the product itself and how it is used in the real world.

The pharmaceutical industry is highly regulated. Prescription drugs sold are subject to highly stringent regulations with respect to their safety and efficacy. This pre-market approval process is much more extensive than, for example, regulations for automobiles or other consumer products that generate considerable risks. This provision would create a more even-handed treatment of pharmaceutical products and reflect a better balance between protecting public safety and recognizing the obligations that pharmaceutical manufacturers have already met to through their compliance with government regulations.

For these reasons, PhRMA supports the adoption of a strong regulatory compliance defense in North Carolina.

PhRMA represents the country's leading pharmaceutical research and biotechnology companies, which are devoted to inventing medicines that allow patients to live longer, healthier and more productive lives. PhRMA companies are leading the way in the search for new cures. PhRMA members alone invested an estimated $49.4 billion in 2010 in discovering and developing new medicines. Industry-wide research and investment reached a record $67.4 billion in 2010.